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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,751	06/20/2003	Randy K. Bledsoe	PU4803US	5089

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,751

Applicant(s)

BLEDSON ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-112 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Status of the Application

- [1]** Claims 1-112 are pending in the application.
- [2]** Receipt of information disclosure statements, filed 5/3/2004 and 3/17/2004, is acknowledged.
- [3]** The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Election/Restrictions

- [4]** Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21 and 30-37, drawn to a crystalline GR polypeptide complex a method of generating a crystallized GR polypeptide complex, classified in class 530, subclass 350.
 - II. Claims 69 and 111-112, drawn to a homology model of an NR or an NR ligand binding domain, classified in class 702, subclass 27.

- III. Claims 95-108, drawn to a data structure, classified in class 702, subclass 27.
- IV. Claims 22-29, drawn to a method for determining a three-dimensional structure, classified in class 702, subclass 27.
- V. Claims 38-45, drawn to a method for identifying a GR modulator, classified in class 702, subclass 27.
- VI. Claims 46-54, drawn to a method of designing a modulator, classified in class 514, subclass 789.
- VII. Claims 55-68, drawn to a method of forming a homology model of an NR, classified in class 702, subclass 27.
- VIII. Claims 70-79, drawn to a second method of designing a modulator, classified in class 514, subclass 789.
- IX. Claims 80-87, drawn to a method of modeling an interaction, classified in class 702, subclass 27.
- X. Claims 88-94, drawn to a third method of designing a modulator, classified in class 702, subclass 27.
- XI. Claim 109, drawn to a method for designing a homology model of an NR ligand binding domain, classified in class 702, subclass 27.
- XII. Claim 110, drawn to a computational method for iteratively generating a homology model of an NR ligand binding domain, classified in class 702, subclass 27.

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[5] If applicants elect the invention of Group I, IV, V, VI, VII, IX, or X, applicants are required under 35 U.S.C. 121 to further elect a single polypeptide selected from the following:

(A) SEQ ID NO:6. (B) SEQ ID NO:8.

[6] If applicants elect the invention of Group VIII, applicants are required under 35 U.S.C. 121 to further elect a single polypeptide selected from the following:

(C) SEQ ID NO:8. (D) SEQ ID NO:10.

[7] The inventions are distinct, each from the other because:

[8] The polypeptides of SEQ ID NO:6 and 8 are structurally distinct and the polypeptide of Group (A) or (B) would not render the other obvious to one of ordinary skill in the art.

[9] The GR ligand binding domain polypeptides of SEQ ID NO:8 and 10 are structurally distinct and the polypeptide of Group (C) or (D) would not render the other obvious to one of ordinary skill in the art.

[10] The crystalline polypeptide of Group I, the homology model of Group II, and the data structure of Group III are chemically unrelated entities capable of separate manufacture, use, and effect.

[11] The crystalline polypeptide of Group I and the method(s) of Group(s) IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the three dimensional structure of the polypeptide can be determined using a soluble protein (by, e.g., NMR spectroscopy) or by homology modeling.

[12] The crystalline polypeptide of Group I and the methods of Groups V, VII, VIII, IX, X, XI, and XII are unrelated to the crystalline polypeptide of Group I as it is neither made nor used by the methods of Groups V, VII, VIII, IX, X, XI, and XII.

[13] The homology model of Group II and the methods of Groups IV, VI, and VIII are unrelated to the homology model of Group II as it is neither made nor used by the methods of Groups IV, VI, and VIII.

[14] The homology model of Group II and the methods of Groups V, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Groups V, IX, and X can be practiced using the template three dimensional model from which the homology model was generated.

[15] The homology model of Group II and the methods of Groups VII, XI, and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant

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case the homology model of an NR can be made using another template amino acid sequence.

[16] The data structure of Group III and the methods of Groups IV, V, VI, VII, VIII, IX, X, XI, and XII are unrelated as it is neither made nor used by the methods of Groups IV, V, VI, VII, VIII, IX, X, XI, and XII.

[17] The methods of Groups IV-XII are independent as they comprise different active method steps, utilize different products, and/or yield different results.

[18] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-XII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In view of the recited limitations of the claims of each invention, a separate sequence and/or patent and non-patent literature search for each invention is required. As such, co-examination of the inventions of Groups I-XII would require a serious burden on the examiner.

[19] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[20] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[21] Claims 17, 28, 36, 42, 50, 59, 75, 84, and 92 will be examined only to the extent the claims read on the elected subject matter.

Rejoinder

[22] The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

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and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER